



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Endpoints for Clinical Trials in Kidney Transplantation; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop to discuss the endpoints for clinical trials of drugs and therapeutic biologics in kidney transplantation. This public workshop is intended to provide information and gain perspective from health care providers, academia, and industry on the role of various clinical, laboratory, histologic, genomic/proteomic, safety, and other endpoints used to evaluate patient and allograft outcome in clinical trials of kidney transplantation. The meeting will include a discussion of measure of patient and graft survival, evaluation of the allograft by histology and biomarkers, glomerular filtration rate or other measures of renal function, evaluation of safety, and other topics. The input from this public workshop will help in developing topics for further discussion and may serve to inform recommendations on potential endpoints in clinical trials of kidney transplantation.

Date and Time: The public workshop will be held on September 10, 2012, from 9 a.m. to 6 p.m., and on September 11, 2012, from 8 a.m. to 3 p.m.

Location: The public workshop will be held at the Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910, 301-589-0800. Seating is limited and available only on a first-come, first-served basis.

Contact Persons: Christine Moser or Ramou Mauer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6209, Silver Spring, MD 20993-0002, 301-796-1300 or 301-796-1600.

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early because space is limited. Seating will be available on a first-come, first-served basis. To register electronically, email registration information (including name, title, firm name, address, telephone, and fax number) to endpoints@fda.hhs.gov. Persons without access to the Internet can call Christine Moser, 301-796-1300, or Ramou Mauer, 301-796-1600, to register.

Persons needing a sign language interpreter or other special accommodations should notify Christine Moser or Ramou Mauer (see Contact Persons) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop regarding potential clinical or surrogate endpoints and biomarkers for clinical trials of drugs and therapeutic biologics in kidney transplantation. This public workshop will include scientific discussion on the following topics:

- Patient and graft survival;
- Allograft rejection, both cellular and antibody-mediated, injury, and recurrent disease;
- Glomerular filtration rate, proteinuria, and other measures of renal function;
- Proteomic, genomic, and immunologic biomarkers;
- Measures of safety, including cardiovascular and metabolic outcomes;
- Medication adherence; and
- Consideration of composite endpoints.

The Agency encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Transcripts will also be available on the Internet at <http://www.fda.gov/Drugs/NewsEvents/ucm305308.htm> approximately 45 days after the workshop.

Dated: August 10, 2012.

Leslie Kux,

Assistant Commissioner for Policy.